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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,909	04/19/2004	Shailaja Kasibhatla	1735.0840002/RWE/ALS	1721

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EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 06/26/2008

Please find below and/or attached an Office communication concerning this application or proceeding.

NOTICE OF NON-RESPONSIVE AMENDMENT

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. However, since the amendment filed on March 17, 2008 is non-responsive for the reasons detailed below, Applicant's submission filed on March 17, 2008, has not been entered. Applicant is reminded that Applicants cannot file an RCE to obtain continued examination on the basis of claims that are independent and distinct from the claims previously claimed and examined as a matter of right (see MPEP 706.07).

Non-Responsive Amendment

2. The amendment filed March 17, 2008, is non-responsive for the following reason:

The amendment filed March 17, 2008, would amend all claims, which were previously drawn to the elected invention, so as to present only claims drawn to a non-elected invention.

The claims, as would be amended, are not readable on the elected invention for the following reasons:

The claims, as would be amended, are directed to a process comprising:

(a) contacting a Transferrin Receptor Related Apoptosis Inducing Protein (TRRAIP) having the amino acid sequence of SEQ ID NOS:1, 2, 3 or 8 and *a*

detectably labeled gambogic acid (GA) or GA-related compound with one or more test compounds; and

(b) *monitoring whether said one or more test compounds displaces said GA or GA-related compound* and binds to said TRRAIP.

In contrast, the originally presented claims, which were drawn to the elected invention, were directed to a process comprising:

a) contacting a Transferrin Receptor Related Apoptosis Inducing Protein (TRRAIP) with the amino acid sequence of SEQ ID NOS:1, 2, 3 or 8 with one or more test compounds; and

(b) monitoring whether said one or more test compounds binds to said TRRAIP.

Accordingly, the claims, as would be amended, are drawn to subject matter that was not encompassed by the claims directed to the invention originally examined on the merits.

In this case, the claims, as would be amended, are directed to materially distinct processes, as compared to the invention originally presented, comprising different process steps, reagents used and/or endpoints from the invention originally presented and the examination of these materially distinct processes could not be made without a serious burden. For example, while the process, as would be amended, similarly recites the method objective of identifying potentially therapeutic anticancer compounds, the claims, as would be amended, further require contacting a detectably labeled gambogic acid or gambogic acid-related compound with one or more test compounds and monitoring whether said one or more test compounds displaces said gambogic acid or gambogic acid-related compound, which was not required by the invention originally presented, because the invention originally presented only recites contacting a Transferrin Receptor Related Apoptosis Inducing Protein with the amino acid sequence of

SEQ ID NOS:1, 2, 3 or 8 with one or more test compounds and monitoring whether said one or more test compounds binds to said TRRAIP. Accordingly, it is apparent that the process, as would be amended, comprises different process steps, reagents used and the monitoring of a different endpoint compared to the invention originally presented. Therefore, while each of these different inventions recites the same method objective, the practice of the each invention to achieve the claimed objective would have different criteria for success.

Furthermore, while the Examiner acknowledges that original claims 26 and 28 recite that the process ***comprises*** gambogic acid having a detectable label or a gambogic acid-related compound having a detectable label, none of the original claims recite an active process step wherein the displacement of gambogic acid having a detectable label or a gambogic acid-related compound having a detectable label was monitored to identify potentially therapeutic anticancer compounds which bind a Transferrin Receptor Related Apoptosis Inducing Protein with the amino acid sequence of SEQ ID NOS:1, 2, 3 or 8. Notably, as set forth in the office action mailed January 26, 2007, these claims were rejected under 35 U.S.C. 112, second paragraph, for this reason. Therefore, it cannot be (as was not) presumed that the originally examined invention encompassed monitoring displacement of gambogic acid having a detectable label or a gambogic acid-related compound having a detectable label to identify potentially therapeutic anticancer compounds which bind a Transferrin Receptor Related Apoptosis Inducing Protein with the amino acid sequence of SEQ ID NOS:1, 2, 3 or 8. In this case, the Examiner submits that had the original claims set forth active process steps drawn to such indirect monitoring methods of monitoring displacement of gambogic acid having a detectable label or a gambogic acid-related compound having a detectable label to identify potentially therapeutic anticancer compounds which bind a Transferrin Receptor Related Apoptosis Inducing Protein, then these methods would have properly been restricted from the invention originally elected. However, once again, the Examiner cannot presume that such claims were drawn to such a patentably

distinct invention, when the claims merely recite that the assay ***comprises*** gambogic acid having a detectable label or a gambogic acid-related compound having a detectable label without setting forth any active process step that requires gambogic acid having a detectable label or a gambogic acid-related compound. For these reasons, it is submitted that the claims, as would be amended, set forth a patentably distinct process for identifying potentially therapeutic anticancer compounds which bind a Transferrin Receptor Related Apoptosis Inducing Protein, as compared to the invention originally presented. If, however, Applicant would like to traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Secondly, the Examiner recognizes that, according to M.P.E.P § 803, there are two separate requirements that must be met to establish the propriety of the restriction between any two inventions. Having shown that these inventions are distinct, it is now necessary to provide reasons why there would be a serious burden on the examiner to examine this newly added invention in addition to the invention elected by originally presentation.

As a first point, because these inventions are distinct for the reasons explained above, it is submitted that each has achieved a different status in the art, as evidenced by their art-recognized divergences. Accordingly, the examination of each of the inventions would require a different search. Moreover, the search required to consider any one of the inventions is not the same, nor is it coextensive with the search necessary to consider any of the others; and therefore any need to search and consider claims directed to more than one of these inventions would constitute a serious burden. Furthermore, it is noted that the claims, as would be amended, are likely to raise different non-prior art issues under 35 U.S.C. §§ 101 and/or 35 U.S.C. 112, first paragraph,

which pertain to the corresponding utility requirement and/or enablement and/or written description requirements because, for example, the genus of test compounds which would bind a Transferrin Receptor Related Apoptosis Inducing Protein with the amino acid sequence of SEQ ID NOS:1, 2, 3 or 8 is not the same as the genus of test compounds that would displace a gambogic acid having a detectable label or a gambogic acid-related compound having a detectable label from a Transferrin Receptor Related Apoptosis Inducing Protein with the amino acid sequence of SEQ ID NOS:1, 2, 3 or 8.

Furthermore, while the Examiner acknowledges that the claims were amended on April 26, 2007 to the patentably distinct process comprising contacting a Transferrin Receptor Related Apoptosis Inducing Protein (TRRAIP) *encoded by* SEQ ID NOS:1, 2, 3 or 8 and a detectably labeled gambogic acid (GA) or GA-related compound with one or more test compounds and monitoring whether said one or more test compounds displaces said GA or GA-related compound and binds to said TRRAIP, as previously presented, such processes could be examined without undue burden. As explained in the previous office action, it was immediately apparent that the previous prior art rejections were rendered moot by this amendment because the prior art cited does not teach or fairly suggest a Transferrin Receptor Related Apoptosis Inducing Protein (TRRAIP) *encoded*[1] by the amino acid sequence of SEQ ID NO:1, 2, 3 or 8. Accordingly, the additional search and consideration required to examine these patentably distinct claims as presented in the amendment filed April 26, 2007 did not create an undue burden on the Examiner. For this reason, a notice of Non-Responsive Amendment was not mailed in response to the amendment filed April 26, 2007, even thought the claims recited a patentably distinct process as compared to the originally elected invention.

Finally, Applicant is reminded that Applicant cannot, as a matter of right, file a request for continued examination (RCE) to obtain continued examination

[1] As explained in the previous Office action mailed October 17, 2007, the term "encode" is defined in the art as meaning "to specify the genetic code for". Accordingly, since SEQ ID NOs: 1, 2, 3 and 8 are amino

on the basis of claims which the examiner holds are drawn to an invention other than the one elected (see MPEP § 706.07, 819 and 821.03).

Accordingly, after entry of the amendment, all remaining claims would be withdrawn from consideration as being directed to non-elected inventions, and therefore the amendment, which presents only claims drawn to such non-elected inventions, is non-responsive and will not be entered. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached on Monday through Friday 7:00 AM to 4:30 PM, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-

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acid sequences and not nucleic acid sequences; and thus, it is immediately apparent that the prior art does

free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully,
Brad Duffy
Examiner, Art Unit 1643
571-272-9935

/Stephen L. Rawlings/
Stephen L. Rawlings, Ph.D.
Primary Examiner, Art Unit 1643

/bd/
June 17, 2008

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not teach a polypeptide encoded by SEQ ID NO: 1, 2, 3 or 8.